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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,744	03/08/2005	Leonidas Diamantopoulos	2667/108	7059
2101 7590 07/25/2008 BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618				
EXAMINER				
HAND, MELANIE JO				
ART UNIT		PAPER NUMBER		
3761				
MAIL DATE		DELIVERY MODE		
07/25/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,744

Applicant(s)

DIAMANTOPOULOS, LEONIDAS

Examiner

MELANIE J. HAND

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. In view of the appeal brief filed on April 22, 2008, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, applicant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then applicant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

Response to Arguments

2. As an initial matter, the ground of rejection of claims 18 and 20 was changed to reflect a new interpretation of the prior art of Diamantopoulos pertaining to the subject matter of claims 18 and 20. It is the change of grounds of rejection of claims 18 and 20 alone that prompted reopening of prosecution by the examiner.

Applicant's arguments filed April 22, 2008 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding the rejection of independent claim 15: Applicant argues that the sensors taught by Diamantopoulos just measure temperature and therefore the sensors do not generate a signal that varies as a function of radial displacement. Applicant further argues that the fact that the temperature varies along a vessel wall at the site of an unstable plaque is not the same as a sensor signal varying as a function of radial displacement. This is not persuasive because claim 15 merely recites "a displacement detector which generates a signal which varies as a function of radial displacement of the at least one resiliently biased projection". The displacement detectors of Diamantopoulos, i.e. sensors, are mounted on the projection. The sensors provide a data signal associated with a temperature reading. The catheter with projection and sensors thereon moves along a vessel wall at the site of a plaque. The projections move inward and outward in the radial direction along the topography of the plaque. At different points while tracing the topography of the wall and plaque thereon, the sensors relay a temperature data signal at that particular radial coordinate. Thus, different temperature readings are transmitted at different radial coordinates. Diamantopoulos explicitly discloses that "it has been reported that unstable and inflamed plaque can cause the temperature of the artery wall to elevate up to 2.5 °C proximate the inflamed plaque." (Page 2, lines 28-30) Thus, in the area proximate the plaque, where the position of the sensor in the radial direction is different than when the sensor is moving along the outer wall of the plaque, the temperature associated with the signal from the sensor is different. The temperature difference can be discerned from the temperature readings at various radial positions, and the difference in location of the sensor in the radial and longitudinal directions will already be noted by the user. Therefore, the at least one displacement detector of Diamantopoulos will generate

a temperature signal that is different from the temperature signal at a different radial coordinate, i.e. it will generate a signal which varies as a function of radial displacement of the sensor and at least one resiliently biased projection.

Applicant continues on use an analogy for support of applicant's argument. This argument containing this analogy is based upon arguments addressed *supra* with respect to the thermal sensors of Diamantopoulos and Diamantopoulos discloses a sensor signal that varies as a function of displacement and is therefore also not persuasive.

Applicant's arguments with regard to dependent claims 21-23 have been fully considered but are not persuasive, as applicant's arguments depend entirely on arguments regarding the rejection of claim 15, which have been addressed *supra*.

Examiner has made a new grounds of rejection noted in sections 6 and 9 of this Examiner's Answer to clarify that, while Diamantopoulos does not explicitly teach a capacitor plate located on the inner face of the at least one projection, it is fairly suggested by Diamantopoulos' teaching that the sensors with plates therein are only "preferably" located on the outer face of the projections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 15-17, 19, 20 and 24-31 rejected under 35 U.S.C. 102(a) as being anticipated by Diamantopoulos et al (WO 01/74263 A1).

With respect to **Claim 15**: Diamantopoulos teaches a catheter comprising at least one resiliently biased projection 11 and at least one detector in the form of thermal sensors 10 that generate a signal that creates temperature data and varies as a function of radial displacement (e.g. due to the presence of a plaque on the vessel wall) relative to the longitudinal axis of said catheter of the at least one projection 11 upon which the detectors are disposed. (Abstract, Page 2, lines 28-33, Page 5, lines 3-8, 30-33)

With respect to **Claim 16**: Detectors 10 are variable capacitor sensors. (Page 13, lines 1-3)

With respect to **Claim 17**: Variable capacitor detectors 10 are permanently attached to the end of each projection 11, i.e. they are mounted on the at least one resiliently biased projection 11. (Page 5, lines 19, 20)

With respect to **Claim 19**: A detector 10 is capable of being formed integrally with its respective projection. (Page 5, lines 19-22)

With respect to **Claim 24**: Diamantopoulos teaches that the projections may not lie in the same plane and are resilient, therefore they are independently biased.

With respect to **Claim 25**: The at least one detector 11 is mounted on a separate projection 10.

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With respect to **Claims 26,27**: The projections 11 are comprised of superelastic material. Diamantopoulos teaches Ni-Ti ternary alloys (i.e. nitinol) as the material for the projections. (Page 4, lines 26-33)

With respect to **Claim 28**: The at least one resiliently biased projections are attached at both ends to the main body of the catheter therefore each projection, when deployed, adopts an arcuate shape along at least part of its length. (Page 4, lines 13-15)

With respect to **Claim 29**: Diamantopoulos teaches a signal processing system wherein each detector 10 transmits an analogue signal to a data interface that is converted to a digital signal, i.e. the signal processing system is electrically coupled to the at least one detector. The data interface 4 is coupled to a PC adapted to detect changes in the signal of the at least one detector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diamantopoulos et al ('263).

With respect to **Claim 18,20**: Diamantopoulos teaches that the capacitor plates are "preferably located on an outer face of the projection". (Page 4, line 20) Examiner interprets this phrase as an implication by Diamantopoulos that the capacitor plates of a sensor can be positioned elsewhere on the projection, i.e. the opposing inner face. Thus, while Diamantopoulos does not explicitly teach an embodiment in which the plates are positioned on an inner face of the respective projection, it would be obvious to one of ordinary skill in the art to modify the device of Diamantopoulos such that a capacitor plate of the at least one sensor is located on an inner face of the at least one projection with a reasonable expectation of success to provide a sensor that is fully capable of providing a thermal topography of a vessel wall for diagnostic purposes.

5. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diamantopoulos et al ('263) in view of Acker (U.S. Patent No. 5,833,608).

With respect to **Claim 21**: Diamantopoulos does not teach that at least one detector comprises an inductance coil and a magnet. Acker teaches a magnetic sensor for determination of position and orientation of a catheter. The sensing volume 32 comprises frame structure 30 housing Helmholtz inductance coil pairs 34,36,38 and galvanomagnetic sensing elements (magnets). Acker teaches that this sensing element determines the position and orientation of a probe within a patient. ('608, Abstract) Therefore, it would be obvious to modify the device of Diamantopoulos such that the at least one displacement detector comprises an inductance coil and magnet as taught by Acker to allow determination of the position and orientation of a probe within a patient, e.g. during a surgical or diagnostic procedure.

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With respect to **Claim 22**: Since Diamantopoulos teaches detectors mounted on at least one resiliently biased projection, the combined teaching of Diamantopoulos and Acker teaches an inductance coil mounted on the at least one resiliently biased projection. The motivation to modify the device of Diamantopoulos such that the at least one displacement detector comprises an inductance coil and magnet as taught by Acker is stated *supra* with respect to claim 21.

With respect to **Claim 23**: Since Diamantopoulos teaches detectors that are integrally formed on the respective projection, the combined teaching of Diamantopoulos and Acker renders the limitation of an inductance coil integrally formed with the at least one resiliently biased projection obvious. The motivation to modify the device of Diamantopoulos such that the at least one displacement detector comprises an inductance coil and magnet as taught by Acker is stated *supra* with respect to claim 21.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761